Bayer

Pharmaceutical Division

Biologicals Business Unit

Carol M. Moore
Vice President
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March 8, 2000

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99N-4784
Proposed Rule, 64 FR 71347
Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification

Dear Sir/Madam:

The purpose of this correspondence is to submit comments and suggestions on the Proposed Rule: Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification.

The comments and suggestions are presented in Appendix 1 immediately following this cover letter.

Please do not hesitate to contact me or Ms. Jean Huxsoll at (510) 705-5117 if you have any questions or comments regarding this correspondence.

Sincerely,

Jean E. Huxsoll FOR

Carol M. Moore
Vice President
Quality Assurance and Regulatory Affairs
Responsible Head/gent

CMM/NJ/slw

Attachment

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99N-4784

March 8, 2000
Docket No. 99N-4784

Appendix 1

Comments/Suggestions

Proposed Rule

Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification

Section II. Procedural Amendments

A. Copyrighted Information Provided in a 510(k)

Copyrighted user/operator manuals are submitted in support of the 510(k) submission, and included as part of the labeling. Under the proposed rule, can the applicant redact the copyrighted user/operator manuals from the labeling?

Under the proposed rule, copyrighted material owned by the applicant is 1) included at the applicant's discretion, and 2) if included will be released in the redacted 510(k). We suggest that the proposed rule be revised to include "copyrighted material owned by the applicant or prepared at the applicant's request" be 1) included at the applicant's discretion, and 2) if included will be released in the redacted 510(k).